

REMARKS

Claim 15 has been currently cancelled and applicants affirm that claim 24 was previously cancelled. Hence claims 2, 6, 10, 16-21 and 28-29 are pending in this application. Said claims are presented for reconsideration.

The examiner objects to the specification because it does not contain section headings, and does not contain the subheadings (e)-(h). However, except for the Claims and Abstract of the Disclosure, which already have headings, nothing in the Rules (35 U.S.C.), the Regulations (37 CFR 1.77(b)) or MPEP (Manual of Patent Examining Procedure) requires headings. Applicants respectfully note that the Arrangement of the Specification is merely a "preferred" one, suggested for applicants' use. It indicates the lettered items "should" (not "shall") be preceded by headings. A number of the lettered items, e.g. (b), (c), (d), (e)(2) and (g), are not even relevant to the present application. Therefore applicants respectfully traverse this objection.

A certified copy of applicants' EP priority application was submitted on April 6, 2000, but the examiner has not acknowledged it on the Office Action Summary page. Applicants respectfully request the examiner to acknowledge its receipt.

Claims 2, 6, 10, 15-21 and 28-29 are rejected under 35 U.S.C. § 112, second paragraph, as indefinite. The examiner asserts the scope of claim 15 is unclear. In view of the cancellation of claim 15, this rejection is moot.

The examiner also asserts the scope of claim 17 is unclear. It is believed that examiner's remarks concern the scope of claim 18. However, applicants note that the aqueous nanodispersion of claim 29 is merely a component in the end formulation, of claim 18 which may be in the form of a solid tablet. Applicants aver there is nothing confusing or unclear about this. Applicants further note that it was the examiner's previous objection to the term "end formulation" that necessitated deletion of the word "end" in claim 18.

The examiner also objects to the term "highly homogeneous" in independent claims 28 and 29. Responsive thereto claims 28 and 29 have been amended in accord with the current rules in which underlining shows additions and strikethrough shows deletions to recite "a monodisperse

nanodispersion having a Gaussian distribution” as disclosed at page 2, 5th full paragraph of the disclosure. No new matter has been added.

No reason for the rejection of claims 2, 6, 10, 16-17 and 19-21 under 35 U.S.C. § 112, second paragraph, as indefinite is given and none is seen.

It is respectfully submitted that all the claims submitted for reconsideration are in good formal order. Reconsideration and withdrawal of the rejection of claims 2, 6, 10, 16-21 and 28-29 under 35 U.S.C. §112, second paragraph is therefore solicited.

Claims 2, 6, 10, 15-21 and 28-29 are rejected under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192. Reconsideration is requested in light of the amendment *supra*, the enclosed declaration and the following remarks.

The teachings of Yiv et al., U.S. Patent 6,245,349, and of Weder WO 96/37192, have been extensively discussed. In the interest of brevity applicants' prior remarks are incorporated by reference.

With regard to the examiner's present comments, the examiner correctly states on page 6, lines 6-7, that Yiv discloses drug delivery systems comprising a polyoxyethylene co-emulsifier (Tween 80, which is polyoxyethylene (20) sorbitan monooleate). Indeed this is the only high HLB surfactant employed in any of the working examples. Weder, WO 96/37192, likewise Weder teaches drug and cosmetic compositions comprising sphingolipids and polyethoxylated sorbitan fatty acid esters such as Tween 80 as essential components. Neither teaches or suggests any advantage to using polyethoxylated compounds according to the present invention in place of polyethoxylated sorbitan fatty acid esters such as Tween 80 as co-emulsifiers.

Polyoxyethylene (20) sorbitan monooleate is a fatty acid derivative of a polyethoxylated carbohydrate. While “polyethoxylated carbohydrates” is recited in independent claims 28 and 29, “fatty acid derivatives of polyethoxylated carbohydrates” is not. It was cancelled in a prior amendment. This cancellation was not based on unclaimed HLB values; it was based on deletion of a specific member of the Markush group formerly recited in these claims.

With this as an introduction, to hasten prosecution, applicants submit another Declaration by Dr. Andreas Supersaxo, an expert in the preparation of drug delivery systems, especially lipid based delivery systems such as liposomes, mixed micelles and microemulsions. Comparison of Examples 2-5 according to the invention, all of which contain polyethoxylated co-emulsifiers having about the same HLB value as that of Example 1 (= Example 2 of WO 96/37192), shows that the use of the co-emulsifier of the present invention leads to nanodispersions having a substantially smaller particle size than that of Example 2 of WO 96/37192. Additionally, Examples 2-5 according to the invention provide far superior dispersions to those wherein non-ethoxylated co-emulsifiers with similar HLB values are used.

As noted *supra*, neither Yiv et al. nor Weder teaches or suggests any advantage to using polyethoxylated compounds according to the present invention in place of polyethoxylated sorbitan fatty acid esters such as Tween 80 as co-emulsifiers. Indeed the expert declares that such improvements could not have been expected by a person skilled in the art.

Reconsideration and withdrawal of the rejection of claims 2, 6, 10, 16-21 and 28-29 under 35 U.S.C. § 103(a) as being unpatentable over Yiv et al., U.S. Patent 6,245,349 in view of Weder WO 96/37192, is respectfully solicited in light of the remarks *supra* and the accompanying declaration.

Since there are no other grounds of objection or rejection, passage of this application to issue with said claims is earnestly solicited.

Applicants submit that the present application is in condition for allowance. In the event that minor amendments will further prosecution, Applicants request that the examiner contact the undersigned representative.

Respectfully submitted,



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Enclosures: Petition for Extension of Time, Declaration

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